REMARKS

Claims 17-37 are all the claims pending in the application.

I. Response to Rejection under 35 U.S.C. § 103

Claims 17-41 stand rejected under 35 U.S.C. §103 as allegedly being unpatentable over Satoshi et al in view of Hill.

The Examiner deems that Satoshi et al. investigates the hybridization process for generating hybrid yeast strains that are highly resistant to high sugar content in bread.

The Examiner also states that "*absent evidence of criticality regarding the presently claimed process and given that Satoshi et al. meets the requirements of the claimed sugar and freeze tolerance by baker's yeast, Satoshi et al. clearly meets the requirements of the present claims*".

Applicants traverse the rejection for the reasons of record and additionally based on the following.

Applicants respectfully submit that the Examiner's analysis is erroneous for at least two reasons:

(1) the differences between the respective processes used in Satoshi et al. and in the present invention are in fact critical; and

(2) the strains disclosed in Satoshi et al. cannot be expected to be as efficient as those of the claimed invention, in view of the disclosure of Satoshi et al.

(1) Criticality of the process used for obtaining the strains of the claimed invention

According to Satoshi et al., clones are produced starting from the single parent TYR strain, and then the clones are hybridized to yield the final strains. In contrast, the strains of the

present invention were obtained by cross-hybridizing a number of commercial strains (used in the bread-making industry) or strains from public collection centers known to have osmotolerance property and/or low sensitivity to mould inhibitors (see paragraph 16 of the application).

There are thus two critical differences in terms of production of strains:

(1) The TYR strain used as the only starting material in Satoshi et al. is a freeze-tolerant strain, but not a sugar-tolerant strain (see section *Materials and Methods*, subsection *Strains and Cultures*). In contrast, strains known to be relatively tolerant to sugar were used as a starting material by the inventors of the present invention.

(2) The process used by the inventors to obtain the claimed strains makes it possible to obtain a much greater variety of final strains than the process disclosed in Satoshi et al. Indeed, the claimed strains were obtained by hybridizing a number of strains of diverse origins, which are totally unrelated. In contrast, Satoshi et al. uses a single parent strain, and all final strains can only differ slightly from the parent strain. Making reference to a vegetal analogy, hybridizing red roses with white roses makes it possible to obtain rose roses, which would be almost impossible by cultivating only red roses or only white roses.

In summary, the strains of Satoshi et al. cannot be expected to be as efficient in terms of tolerance to sugar as the claimed strains. It would be extremely unlikely for a strain obtained owing to the method of Satoshi et al. to be as sugar-tolerant as the (selected) strains obtained by the inventors and claimed in the present application, due to the critically different methods employed.

This analysis as to the influence of the process on the products obtained is confirmed by looking at the tests performed on the respective products.

(2) Efficiency of the strains

Indeed, looking at the properties of the strains described in Satoshi et al., it cannot be inferred that these strains have sugar-tolerance performances comparable to those of the claimed invention.

First of all, in Satoshi et al. the strains are cultivated in batch. A pre-cultivation step is performed using the YPD medium; then a cultivation step is performed on a growth medium containing 3% of sugar, 0.046% of KH_2PO_4 and 0.193% of urea; finally, the yeast cells are centrifuged and filtered (see section *Materials and Methods*, subsection *Strains and Cultures*).

This is a mode of production which is used only in laboratories, for research purposes, and which stands in sharp contrast with an industrial mode of production.

In a laboratory-type batch production of yeast, the types and amounts of nutrients are closely controlled. So is the possible presence of compounds that are toxic for the yeast. On the contrary, at the industrial level, where a fed-batch mode of production is used, there is no such tight control of the nutrients and toxic compounds. Accordingly, the metabolism of the yeast is known to be very different in a laboratory-type batch process *vs.* in an industrial-type fed-batch process.

As a result, the skilled person knows that a yeast strain which has a certain efficiency when produced in a laboratory batch process will generally not have the same efficiency in an industrial fed-batch process (assuming it can be produced at all). In fact, in the process of developing new yeast strains, laboratory tests are generally performed first, but it is well known

that most of the strains effective at the laboratory level will actually be useless at the industrial level.

Since the strains of Satoshi et al. were only tested in optimal conditions in laboratory-scale experiments, it cannot be predicted or expected that any of them will retain their properties when used in actual industrial conditions.

This is however not the case for the strains of the claimed invention, since these strains were produced in actual industrial conditions. See *e.g.,* par. 39-48 of the specification in this respect.

Turning now to the respective performances of the yeast in the presence of sugar in the claimed invention *vs.* in Satoshi et al., it is agreed that the conditions are not the same and that a direct comparison cannot be made. However, an *indirect* comparison can be made and it unambiguously shows that the strains of the claimed invention perform better than the strains of Satoshi et al.

In Satoshi et al., performance in the presence of sugar is assessed by measuring the CO_2 production in dough using a Fermograph (see section *Materials and Methods*, subsection *Frozen Dough System*). In the present application, performance in the presence of sugar is assessed by measuring the proof time. The better performing the yeast is, the more CO_2 is produced, and the shorter the proof time is.

Generally, if one compares a yeast strain A with a yeast strain B, the difference in CO_2 production between the strains can be expected to be roughly proportional to the difference in proof time between the same strains. In other terms, if strain B produces 10% more CO_2 than strain A, then the proof time of the dough containing strain B can be expected to be roughly 10%

shorter than the proof time of the dough containing strain A, assuming a same dough composition, and in particular a same sugar content and a same yeast dry matter content.

In Satoshi et al., the dough contains 3 g of yeast per 100 g of flour (see Table 1), which amounts to 990 mg of yeast dry matter per 100 g of flour (given the yeast moisture of 67%, see section *Materials and Methods*, subsection *Strains and Cultures*).

In the test PT2 used in the present application, the yeast content is 9 g per 100 g of flour, which amounts to 2880 mg of yeast dry matter per 100 g of flour (given a yeast dry matter content of 32 %).

Now, both the amount of CO_2 produced and the proof time can be expected to be roughly proportional to the yeast dry matter content of the dough.

Taking the above into account, the following table is a side-by-side comparison of the tests performed in Satoshi et al. and in the present application:

	Strain 893 **(Satoshi et al.)** "*best strain*" of Table 4	Strain CNCM I-2971 **(claimed invention)**	Strain CNCM I-3143 **(claimed invention)**
Amount of sugar in dough	30%	40%	40%
Relative improvement of leavening activity relative to reference strain	Approx. **4%** (increase in CO_2 production generated by 990 mg of yeast dry matter)	**8.5%** (decrease in proof time in PT2 test, assuming a yeast dry matter amount of 990 mg instead of 2880 mg)	**12%** (decrease in proof time in PT2 test, assuming a yeast dry matter amount of 990 mg instead of 2880 mg)
Nature of reference strain	Commercial strain KY5531 or KY5649	Strain NCYC 996 commonly used as a standard for sweet dough	Strain NCYC 996 commonly used as a standard for sweet dough

In summary, the efficiency of the yeast strains of the claimed invention is markedly better than that of the strains of Satoshi et al. because the improvement in terms of leavening activity afforded by the claimed strains is 2 to 3 times better than that afforded by the strains of Satoshi et al.[1], although all test conditions are more severe for the claimed strains than for those of Satoshi et al., in particular since:

- the amount of sugar in the dough is 33% higher in the test of the present application than in Satoshi et al. (40% instead of 30%)[2];
- the reference strain used in the present application (NCYC 996) is known to be already relatively efficient on sweet dough (see par.24 of the application), which is not the case of the reference strains used in Satoshi et al.; and
- the claimed strains were produced in actual industrial-type conditions of production, whereas in Satoshi et al. more favorable laboratory-type batch conditions are used.

The Examiner notes that the USPTO does not possess the facilities to test each strain of microorganism so as to achieve a direct comparison of the strains of Satoshi et al. with those of the claimed invention.

On the other hand, it would be very difficult for the Applicant as well to perform such comparative tests, if only because the hybrid strains mentioned in Satoshi et al., are not commercial strains and can probably not be obtained by the Applicant in the first place.

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[1] Assuming a similar yeast dry matter content.

[2] In this respect it should be emphasized that the sensitivity of yeast to sugar is non-linear, especially at high sugar contents.

It would be unfair if such a situation should penalize the Applicant, given that there are many pointers in Satoshi et al. which indicate that the strains taught in this document are less efficient in the presence of sugar than those of the claimed invention. It is the Examiner's burden to show that the strains of Satoshi et al. are similar to those of the claimed invention before the Examiner can assert that said strains would inherently possess the claimed properties. "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic <u>necessarily</u> flows from the teachings of the applied prior art." MPEP § 2112(IV). Applicants respectfully submit that the Examiner has not met his burden for at least the reasons set forth above.

As a final remark, Applicants note that the shortcomings of Satoshi et al. may not be solved by Hill, since Hill does not deal with the production of new sugar-tolerant strains.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection.

II. Conclusion

In view of the foregoing, the Applicant believes all claims now pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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